

## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of

Atty Dkt. 1579-601

HAYNES, Barton F.

Serial No. 09/956,940

Filed: September 21, 2001

Title: USE OF SYNTHETIC PEPTIDES TO INDUCE TOLERANCE TO PATHOGENIC T  
AND B CELL EPITOPES OF AUTOANTIGENS OR INFECTIOUS AGENTS

Commissioner for Patents

P.O. Box 1450

Alexandria, VA 22313-1450

Sir:

**SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT**

This is a response/amendment/letter in the above-identified application and includes an attachment which is hereby incorporated by reference and the signature below serves as the signature to the attachment in the absence of any other signature thereon.

 **Correspondence Address Indication Form Attached.****Fees are attached as calculated below:**

Total effective claims after amendment 0 minus highest number  
previously paid for 20 (at least 20) = 0 x \$ 18.00 \$ 0.00

Independent claims after amendment 0 minus highest number  
previously paid for 3 (at least 3) = 0 x \$ 86.00 \$ 0.00

If proper multiple dependent claims now added for first time, add \$290.00 (ignore improper) \$ 0.00

Petition is hereby made to extend the current due date so as to cover the filing date of this paper and attachment(s) (\$110.00/1 month; \$420.00/2 months; \$950.00/3 months) \$ 0.00

Terminal disclaimer enclosed, add \$ 110.00 \$ 0.00

First/second submission after Final Rejection pursuant to 37 CFR 1.129(a) (\$770.00)  
 Please enter the previously unentered , filed  
 Submission attached

**Subtotal** \$ 0.00

If "small entity," then enter half (1/2) of subtotal and subtract  
 Applicant claims "small entity" status.  Statement filed herewith -\$ 0.00

Rule 56 Information Disclosure Statement Filing Fee (\$180.00) \$ 180.00

Assignment Recording Fee (\$40.00) \$ 0.00

Other: \$ 0.00

**TOTAL FEE TO BE DEBITED** \$ 180.00

The Commissioner is hereby authorized to charge any deficiency, or credit any overpayment, in the fee(s) filed, or asserted to be filed, or which should have been filed herewith (or with any paper hereafter filed in this application by this firm) to our Account No. 14-1140. A duplicate copy of this sheet is attached.

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NIXON & VANDERHYE P.C.  
 By Atty: Mary J. Wilson, Reg. No. 32,955

Signature: Mary J. Wilson

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE  
DEC 12 2003  
U.S. TRADEMARK OFFICE

In re Patent Application of

HAYNES, Barton F.

Serial No. 09/956,940

Filed: September 21, 2001

Confirmation No. 4369

Atty. Ref.: 1579-601

Group: 1644

Examiner: Schwadron, R.

For: USE OF SYNTHETIC PEPTIDES TO INDUCE  
TOLERANCE TO PATHOGENIC T AND B CELL  
EPITOPES OF AUTOANTIGENS OR INFECTIOUS  
AGENTS

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Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

December 12, 2003

Sir:

**SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT**

1. **PTO-1449 Pursuant to 37 CFR 1.97(b)**  
[within 3 months of filing or prior to 1st Office Action on the merits]  
N/C

2.(a) **Statement Pursuant to 37 CFR 1.97(c)**  
[before Final Office Action or Allowance (requires Rule 97(e)  
Statement or Rule 17(p) fee)]  
N/C

2 .(b) **Fee Payment Pursuant to 37 CFR 1.97(c)**  
[before Final Office Action or Allowance (requires Rule 97(e)  
Statement or Rule 17(p) fee)]  
\$180.00

3. **Pursuant to 37 CFR 1.97(d)**  
[after Final Office Action or Allowance (requires Rule 97(e)  
Statement and Rule 17(p) fee), but before final fee payment]  
\$180.00

The following are submitted in the above-identified application in compliance with  
37 C.F.R. §§ 1.97 and 1.98:

HAYNES, Barton F.  
Serial No. 09/956,940  
December 12, 2003

4. A list of documents on Form PTO-1449 together with copies of each identified document and a translation or a concise explanation of each non-English language document (such as a Search Report) is enclosed herewith.

This paper is submitted in accordance with:

5. 37 CFR 1.97(b): [within 3 months of filing or prior to 1<sup>st</sup> Office Action]

6. 37 CFR 1.97(c): [before Final Office Action or Allowance, whichever is earlier]; and

a) The required Statement made in item 8 below; or

b) The \$180.00 fee specified in 37 CFR §1.17(p) for submission of this Information Disclosure Statement is authorized in item 9 below.

7. 37 CFR §1.97(d): [after Final Office Action or Allowance (requires Rule 97(e) Statement and Rule 17(p) fee), but before final fee payment]; and

a) The fee (\$180.00) required by 37 CFR §1.17(p) is submitted herewith; and

b) The required Statement is stated in item 8 below.

8. Statement under 37 CFR 1.97(e)

a) The undersigned attorney of record hereby certifies under 37 C.F.R. §1.97(e) that each item of information contained in this Information Disclosure Statement was first cited in a communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this Information Disclosure Statement (each item contained in this IDS was the first citation of that item by a foreign patent office in a counterpart foreign application which occurred no more than three months prior to the filing of this IDS); or

b) No item of information contained in this Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing this Statement, after making reasonable inquiry, no item of information contained in this Statement was known to any individual designated in 37 CFR §1.56(c) more than three months prior to the filing of this Information Disclosure Statement.

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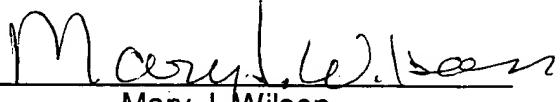
\* Except for Hu et al (Nature 1986), Fox and Butini et al – as noted on the PTO-1449 Form (page 3), copies can be found in the identified application.

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December 12, 2003

9. Please charge all deficiency fees associated with the submission of this Information Disclosure Statement and any other fees applicable to this application to Deposit Account No. 14-1140. An original and one (1) copy of this document are enclosed.

Respectfully submitted,  
NIXON & VANDERHYE P.C.

By:

  
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| <b>CITATION</b>                   |  | 1579-601           | 09/956,940 |
| (Use several sheets if necessary) |  | APPLICANT          |            |
|                                   |  | HAYNES, Barton F.  |            |
|                                   |  | FILING DATE        | GROUP      |
|                                   |  | September 21, 2001 | 1644       |
| <b>U.S. PATENT DOCUMENTS</b>      |  |                    |            |

DEC 12 2003  
PATENT & TRADEMARK OFFICE

| *EXAMINER<br>INITIAL | DOCUMENT NUMBER | DATE   | NAME          | CLASS | SUBCLASS | FILING DATE<br>IF APPROPRIATE |
|----------------------|-----------------|--------|---------------|-------|----------|-------------------------------|
|                      | 4,812,556       | 3/1989 | Vahlne et al  |       |          |                               |
|                      | 4,659,678       | 4/1987 | Forrest et al |       |          |                               |
|                      | 4,520,113       | 5/1985 | Gallo et al   |       |          |                               |
|                      | 4,956,273       | 9/1990 | Kennedy et al |       |          |                               |
|                      | 4,725,669       | 2/1988 | Essex et al   |       |          |                               |

**FOREIGN PATENT DOCUMENTS**

| DOCUMENT    | DATE   | COUNTRY | TRANSLATION |          |     |    |
|-------------|--------|---------|-------------|----------|-----|----|
|             |        |         | CLASS       | SUBCLASS | YES | NO |
| 0 255 190   | 2/1988 | EPO     |             |          |     |    |
| WO 87/02775 | 5/1987 | WIPO    |             |          |     |    |
| WO 91/04051 | 4/1991 | WIPO    |             |          |     |    |
| WO 88/05783 | 8/1988 | WIPO    |             |          |     |    |
| 0 273 716   | 7/1988 | EPO     |             |          |     |    |
| WO 91/04273 | 4/1991 | WIPO    |             |          |     |    |

**OTHER DOCUMENTS (including Author, Title, Date, Pertinent pages, etc.)**

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|  | Hart et al, "Synthetic Peptides Containing T and B Cell Epitopes from Human Immunodeficiency Virus Envelope gp120 Induce Anti-HIV Proliferative Responses and High Titers of Neutralizing Antibodies in Rhesus Monkeys", <i>The Journal of Immunology</i> 145(8): 2677-2685 (1990)    |
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\*Examiner \_\_\_\_\_ Date Considered \_\_\_\_\_

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| DEC 12 2003<br>PATENT & TRADEMARK OFFICE  |  | APPLICANT         |            |
| (Use several sheets if necessary)   |  | HAYNES, Barton F. |            |
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| <b>OTHER DOCUMENTS (including Author, Title, Date, Pertinent pages, etc.)</b>   |  |                   |            |
| *EXAMINER INITIAL   |  |                   |            |
| <p>Krohn et al, "Specific cellular immune response and neutralizing antibodies in goats immunized with native or recombinant envelope proteins derived from human T-lymphotropic virus type IIIB and in human immunodeficiency virus-infected men", Proc. Natl. Acad. Sci. USA 84:4994-4998 (1987)</p> <p>Starcich et al, "Identification and Characterization of Conserved and Variable Regions in the Envelope Gene of HTLV-III/LAV, the Retrovirus of AIDS", Cell 45:637-648 (1986)</p> <p>Robey et al, "Prospect for prevention of human immunodeficiency virus infection: Purified 120-kDa envelope glycoprotein induces neutralizing antibody", Proc. Natl. Acad. Sci. USA 83:7023-7027 (1986)</p> <p>Wang et al, "Detection of antibodies to human T-lymphotropic virus type III by using a synthetic peptide of 21 amino acid residues corresponding to a highly antigenic segment of gp41 envelope protein", Proc. Natl. Acad. Sci. USA 83:6159-6163 (1986)</p> <p>Sodroski et al, "Role of the HTLV-III/LAV envelope in syncytium formation and cytopathicity", Nature 322:470-474 (1986)</p> <p>Dalgleish et al, "The CD4 (T4) antigen is an essential component of the receptor for the AIDS retrovirus", Nature 312:763-767 (1984)</p> <p>Javaherian et al, "Principal neutralizing domain of the human immunodeficiency virus type 1 envelope protein", Proc. Natl. Acad. Sci. USA 86:6768-6772 (1989)</p> <p>Chakrabarti et al, "Expression of the HTLV-III envelope gene by a recombinant vaccinia virus", Nature 320:535-540 (1986)</p> <p>Zarling et al, "Proliferative and Cytotoxic T Cells to AIDS Virus Glycoproteins in Chimpanzees Immunized with a Recombinant Vaccinia Virus Expressing AIDS Virus Envelope Glycoproteins", The Journal of Immunology 139(4):988-990 (1987)</p> <p>Hu et al, "Effect of immunization with a vaccinia-HIV env recombinant on HIV infection of chimpanzees", Nature 328:721-723 (1987)</p> <p>Ratner et al, "Complete nucleotide sequence of the AIDS virus, HTLV-III", Nature 313:277-284 (1985)</p> <p>Palker et al, "A conserved region at the COOH terminus of human immunodeficiency virus gp120 envelope protein contains an immunodominant epitope", Proc. Natl. Acad. Sci. USA 84:2479-2483 (1987)</p> <p>Newmark, "Problems with AIDS vaccines", Nature 324:304-305 (1986)</p> <p>Norman, "AIDS Virus Presents Moving Target", Science 230:1357-1358 (1985)</p> <p>Takahashi et al, "Structural Requirements for Class I MHC Molecule-Mediated Antigen Presentation and Cytotoxic T Cell Recognition of an Immunodominant Determinant of the Human Immunodeficiency Virus Envelope Protein", The Journal of Experimental Medicine 170:2023-2035 (1989)</p> <p>Palker et al, "Polyvalent Human Immunodeficiency Virus Synthetic Immunogen Comprised of Envelope gp120 T Helper Cell Sites and B Cell Neutralization Epitopes", The Journal of Immunology 142(10):3612-3619 (1989)</p> <p>Girard et al, "Immune Response of Chimpanzees to Active Immunization Against HIV-1", J. of Cell. Biochemistry, UCLA Symp. on Mol. and Cell Biol., page 150 (1990) – Abstract No. L415</p> <p>Weinhold et al, "Cell-Mediated Cytolytic Reactivities Against Epitopes Contained Within the V3 Region of HIV-1 GP120", J. of Cell. Biochemistry, UCLA Symp. on Mol. and Cell Biol., page 180 (1990) – Abstract No. L550</p> <p>Hart et al, "Neutralizing Anti-HIV Antibodies are Induced in Rhesus Monkeys Immunized with Hybrid Synthetic Peptides (TI-SP10) Containing T and B Cell Epitopes from HIV gp120", J. of Cell. Biochemistry, UCLA Symp. on Mol. and Cell Biol., page 134 (1990) – Abstract No. L315</p> <p>Palker et al, "Type-specific neutralization of the human immunodeficiency virus with antibodies to env-encoded synthetic peptides", Proc. Natl. Acad. Sci. USA 85:1932-1936 (1988)</p> <p>Gallaher, "Detection of a Fusion Peptide Sequence in the Transmembrane Protein of Human Immunodeficiency Virus", Cell 50:327-328 (1987)</p> |  |                   |            |
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| *EXAMINER INITIAL   |   |                    |            |
|   | Hu et al, "Expression of AIDS virus envelope gene in recombinant vaccinia viruses", Nature 320(6062):537-540 (1986) – cited in parentmost Application No. 07/093,854 – Abstract attached hereto   |                    |            |
|   | Fox, "No Winners Against AIDS", Biotechnology 12:128 (1994) – cited by Examiner in Application No. 08/546,515   |                    |            |
|   | Butini et al, "Comparative Analysis ...", J. Cell Biochem. Suppl. 18B, J306 (1994) – cited by Examiner in Application No. 08/546,515  |                    |            |
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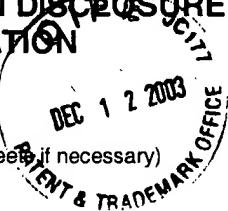
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| <b>*EXAMINER INITIAL</b>   |  |                                   |                          |
| <p>Takai et al, "Prokaryotic Expression of the Thyrotropin Receptor and Identification of an Immunogenic Region of the Protein Using Synthetic Peptides", Biochemical and Biophysical Research Communications 179(1):319-326 (1991)</p> <p>Piraphatdist et al, "Possible Binding Site of Thyrotropin Binding Inhibitor Immunoglobulin (TBII) on the Thyrotropin (TSH) Receptor, Which is Different from TSH Binding Site", Biochemical and Biophysical Research Communications 172(2):529-536 (1990)</p> <p>Hendricks et al, "Alterations in the Antigenic Structure of Two Major HSV-1 Glycoproteins, gC and gB, Influence Immune Regulation and Susceptibility to Murine Herpes Keratitis", The Journal of Immunology 142(1):0263-0269 (1989)</p> <p>Weigle, "The Role of the Physical State of Human Gamma Globulin in the In Vivo and In Vitro Induction of Immunological Tolerance", eds. Sercarz and Berzofsky, CRC Press, Inc. Boca Raton, Florida, Immunogenicity of Protein Antigens: Repertoire and Regulation Vol. II, Chapter 5G, pgs. 51-57</p> <p>Gahring and Weigle, "The Regulatory Effects of Cytokines on the Induction of a Peripheral Immunologic Tolerance in Mice", The Journal of Immunology 145(5):1318-1323 (1990)</p> <p>Milich et al, "Distinction Between Immunogenicity and Tolerogenicity Among HbcAg T Cell Determinants", The Journal of Immunology 143(10):3148-3156 (1989)</p> <p>Sprent et al, "T Cell Reactivity to MHC Molecules: Immunity Versus Tolerance", Science 248:1357-1363 (1990)</p> <p>Lee and Sehon, "Suppression of Reaginic Antibodies with Modified Allergens", Int. Archs Allergy Appl. Immun. 56:159-170 (1978)</p> <p>Lee and Sehon, "Suppression of Reaginic Antibodies with Modified Allergens", Int. Archs Allergy Appl. Immun. 56:193-206 (1978)</p> <p>Wie et al, Suppression of Reaginic Antibodies with Modified Allergens", Int. Archs Allergy Appl. Immun. 64:84-99 (1981)</p> <p>Lee et al, Suppression of Reaginic Antibodies with Modified Allergens", Int. Archs Allergy Appl. Immun. 64:100-114 (1981)</p> <p>Abuchowski et al, "Alteration of Immunological Properties of Bovine Serum Albumin by Covalent Attachment of Polyethylene Glycol", The Journal of Biological Chemistry 252(11):3578-3581 (1977)</p> <p>Abuchowski et al, "Effect of Covalent Attachment of Polyethylene Glycol on Immunogenicity and Circulating Life of Bovine Liver Catalase", The Journal of Biological Chemistry 252(11):3582-3586 (1977)</p> <p>Abuchowski et al, "Cancer Therapy with Chemically Modified Enzymes. I. Antitumor Properties of Polyethylene Glycol-Asparaginase Conjugates", Cancer Biochem. Biophys. 7:175-186 (1984)</p> <p>Williams, "T Cell Inactivation Linked to Ras Block", Science 271:1234 (1996)</p> <p>Lin et al, "Inhibition of Nuclear Translocation of Transcription Factor NF-KB by a synthetic Peptide Containing a Cell Membrane-permeable Motif and Nuclear Localization Sequence", The American Society for Biochemistry and Molecular Biology, Inc. 270(24):14255-14258 (1995)</p> <p>Edgington, "How Sweet It is: Selectin-Mediating Drugs", Bio/Technology 10:383-389 (1992)</p> <p>Fahey and Schooley, "Status of immune-based therapies in HIV infection and AIDS", Clin. exp. Immunol. 88:1-5 (1992)</p> <p>Woodrow et al, "p21<sup>ras</sup> Function Is Important for T Cell Antigen Receptor and Protein Kinase C Regulation of Nuclear Factor of Activated T Cells", The Journal of Immunology 150(9):3853-3861 (1993)</p> <p>Björling et al, "Hyperimmune antisera against synthetic peptides representing the glycoprotein of human immunodeficiency virus type 2 ca mediate neutralization and antibody-dependent cytotoxic activity", Proc. Natl. Acad. Sci. USA 88:6082-6086 (1991)</p> |  |                                   |                          |

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| INFORMATION DISCLOSURE<br>CITATION  |  | ATTY. DOCKET NO.<br>1579-601      | SERIAL NO.<br>09/956,940 |   |   |   |  |   |  |   |   |   |  |   |   |   |   |   |  |   |   |    |  |    |   |    |  |    |  |    |  |    |   |    |  |    |   |    |  |    |   |    |  |
|   |  | APPLICANT<br>HAYNES, Barton F.    |                          |   |   |   |  |   |  |   |   |   |  |   |   |   |   |   |  |   |   |    |  |    |   |    |  |    |  |    |  |    |   |    |  |    |   |    |  |    |   |    |  |
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|  <b>OTHER DOCUMENTS (including Author, Title, Date, Pertinent pages, etc.)</b>   |  |                                   |                          |   |   |   |  |   |  |   |   |   |  |   |   |   |   |   |  |   |   |    |  |    |   |    |  |    |  |    |  |    |   |    |  |    |   |    |  |    |   |    |  |
| *EXAMINER INITIAL   |  |                                   |                          |   |   |   |  |   |  |   |   |   |  |   |   |   |   |   |  |   |   |    |  |    |   |    |  |    |  |    |  |    |   |    |  |    |   |    |  |    |   |    |  |
| <table border="1" style="width: 100%; border-collapse: collapse;"> <tr><td style="width: 10%;">1</td><td>Sanchez-Pescador et al, "Nucleotide Sequence and Expression of an AIDS-Associated Retrovirus (ARV-2)", Science 227:484-492 (1985)</td></tr> <tr><td>2</td><td>Berzofsky, "Progress toward Artificial Vaccines for HIV", Vaccines 92:41-50 (1992)</td></tr> <tr><td>3</td><td>Haynes et al, "Use of Synthetic Peptides in Primates to Induce High-Titered Neutralizing Antibodies and MHC Class I-Restricted Cytotoxic T Cells Against AIDS Retroviruses: An HLA-Based Vaccine Strategy", 1993 Clinical Research Abstract Form</td></tr> <tr><td>4</td><td>Leclerc et al, "A synthetic vaccine constructed by copolymerization of B and T cell determinants", Eur. J. 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| 15  | Cleghorn et al, "Preparations for HIV-1 Vaccine Efficacy Trials in Trinidad", Prevention and Treatment of AIDS, pg. 156, Abstract J 404  |                                   |                          |   |   |   |  |   |  |   |   |   |  |   |   |   |   |   |  |   |   |    |  |    |   |    |  |    |  |    |  |    |   |    |  |    |   |    |  |    |   |    |  |
| 16  | di Marzo Veronese et al, "Epitope Mimicry by Display of Foreign Peptides on the Surface of Filamentous Bacteriophage", Prevention and Treatment of AIDS, pg. 156, Abstract J 405   |                                   |                          |   |   |   |  |   |  |   |   |   |  |   |   |   |   |   |  |   |   |    |  |    |   |    |  |    |  |    |  |    |   |    |  |    |   |    |  |    |   |    |  |
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| 20  | Brown and Weiser, "HIV Infections Cast Pall Over Expanding Vaccine Experiments", The Washington Post, pg. A7, Monday, May 30, 1994   |                                   |                          |   |   |   |  |   |  |   |   |   |  |   |   |   |   |   |  |   |   |    |  |    |   |    |  |    |  |    |  |    |   |    |  |    |   |    |  |    |   |    |  |

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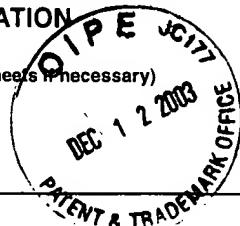
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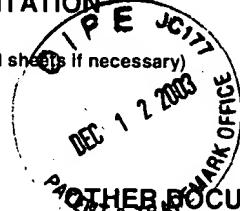
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| WO 93/04697 ✓ | 3/1993  | WIPO    |       |          |     |    |
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